K110384

SECTION 5

510(K) Summary

MAY - 3 2011

SUBMITTING COMPANY: Dilon Technologies Inc
Address: 12050 Jefferson Ave, Suite 340
Newport News, VA 23606
Telephone: 757-269-4910
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Submitted by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
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Email: Duncan@paladinmedical.com

CONTACT PERSON: Elaine Duncan

DATE PREPARED (revised): March 31, 2011

TRADE NAME: Dilon 6800 Acella

COMMON NAME: Scintillation Camera

CLASSIFICATION NAME: camera, scintillation (gamma)

PRO CODE: IYX

SUBSTANTIALLY EQUIVALENT TO:

~~SPECIAL~~ **510(k)** Modifications to Dilon 2000 (now known as Dilon 6800, K984466 for a technology change. The primary difference is the change in detector technology from photomultiplier tubes to the photodiode technology, previously cleared by FDA in K100838. Dilon Technologies, Inc. has demonstrated that there are no new safety issues due to the change in detector technology and has shown the performance of the Acella to be equivalent to the Dilon 6800 camera and the predicate detector technology and has not altered the fundamental technology of the original Dilon 6800.

DESCRIPTION of the DEVICE:

The *Dilon 6800 Acella* (Acella) is a modification to the Dilon 2000 (now known as the Dilon 6800), a high resolution, small field of view, portable gamma camera designed for general use in imaging radio pharmaceuticals. The *Acella* has a larger field-of-view than the Dilon 6800 and replaces photomultiplier tubes with photodiodes. Both technologies convert visible light photons generated by scintillation crystals into electronic signals.

INDICATIONS FOR USE:

The *Dilon 6800 Acella* Digital Gamma Camera is intended to be used to measure and image the distribution of selected single photon emitting radioisotopes in the human body. The resulting images are intended to be reviewed by qualified medical personnel.

SUMMARY of TESTING and Design Control Compliance:

Performance testing has been provided for material change on collimator surface, software, EMC/EMI testing and other performance requirements. Verification testing was drawn from the experience with the Dilon 6800, risk analysis of software and hardware changes and conformance with international standards. Testing has demonstrated that the Acella, with the larger Field of View, has met predetermined success criteria according to established protocols and as documented through Design Control and Review. The results show the Acella is substantially equivalent to the Dilon 6800 camera and the predicate photodiode detector technology. No new safety issues are introduced as a result of the technology change.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Dilon Technologies, Inc.
% Ms. Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
STILLWATER MN 55082

MAY - 3 2011

Re: K110384
Trade/Device Name: Dilon 6800 Acella
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: II
Product Code: IYX
Dated: April 1, 2011
Received: April 4, 2011

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dilon Technologies, Inc.
% Ms. Elaine Duncan
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STILLWATER MN 55082

MAY 10 2011

Re: K110384
Trade/Device Name: Dilon 6800 Acella
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: April 1, 2011
Received: April 4, 2011

Dear Ms. Duncan:

This letter corrects our substantially equivalent letter of May 3, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (If known):

Device Name: Dilon 6800 Acella

Indications For Use: K110384

The Dilon 6800 Acella Digital Gamma Camera is intended to be used to measure and image the distribution of selected single photon emitting radioisotopes in the human body. The resulting images are intended to be reviewed by qualified medical personnel.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110384

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